



01-07-05

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Application No.: 10/615,213

Docket No.: 01946/100G906-US2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
William E. BAY et al.

Application No.: 10/615,213

Confirmation No.: 8060

Filed: July 7, 2003

Art Unit: 1625

For: DISODIUM SALTS, MONOHYDRATES, AND  
ETHANOL SOLVATES FOR DELIVERING  
ACTIVE AGENTS

Examiner: Paul J. KILLOS

**REQUEST FOR WITHDRAWAL OF NOTICE OF ABANDONMENT**

MAIL STOP PETITION  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants in the above-identified patent application have received a NOTICE OF ABANDONMENT, mailed December 29, 2004 (copy enclosed as Exhibit A), advising that the application has been abandoned due to applicants' alleged failure to timely respond to an Office Action mailed June 23, 2004. The last day to timely file a Response to this Office Action was December 23, 2004 (with a three-month extension of time).

The Patent Office is respectfully advised that on December 23, 2004, Applicants submitted pursuant to 37 C.F.R. § 1.10, *inter alia*, an Amendment in Response to a Non-Final Office Action, a Three Month Request Extension of Time under 37 C.F.R. § 1.136(a), and Check No. 7124 for \$1,020 to cover the three month extension of time fee. In support thereof Applicants enclose the following:

(a) A copy of the originally-deposited postcard listing, *inter alia*: "Amendment in Response to Non-Final Office Action"; "Three Month Request for Extension of Time Under 37

C.F.R. § 1.136(a)"; and "Check No. 7124 for \$1020.00"; showing the number of the "Express Mail" mailing label thereon (EV 382054156) (Exhibit B);

(b) A copy of the Amendment In Response to Non-Final Office Action, a Petition for a Three Month Extension of Time under 37 C.F.R. § 1.136(a), and a Certificate of Express Mailing under 37 C.F.R. § 1.110, as timely filed on December 23, 2004 (Exhibit C);

(c) A copy of the "Express Mail" mailing label showing the "date-in," on the "Express Mail" mailing label (December 23, 2004) entered by the U.S. Postal Service. (Exhibit D);

(d) A "Track & Confirm" Report from the U.S. Postal Service, indicating that Express Mail Package EV 382054156 was delivered at 8:31 a.m. on December 27, 2004 to Patent Office, Alexandria, VA 22313, and signed for by M. Boston (Exhibit E);

(f) A declaration signed by Bruce W. Lee, docketing clerk at Darby & Darby P.C., describing the procedure followed by our Docketing Department in the handling of mail to the Patent Office (Exhibit F).

Applicants note that a return post-card has not yet been received by Applicant's counsel. The copies of the correspondence (Exhibits B and C), the "Express Mail" mailing label (Exhibit D), and the official notation entered by the USPS (Exhibit D) are true copies of the originally mailed correspondence, original "Express Mail" mailing label, and official notation entered by the USPS.

We contacted our bank, Citibank, N.A., to determine if Check No. 7124 in the amount of \$1020.00 has cleared. According to Citibank records, there is no indication that Check No. 7124 has cleared, although we understand that it usually takes about two weeks for such records to be updated. Applicants do not submit a second check herewith, since it is believed that Check No. 7124 is in the PTO awaiting processing (or has already been processed). If any additional fees are due, the Commissioner is hereby authorized to charge them to deposit account No. 04-0100.



Attorney Docket No.: 01946/100G906-US2

# Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. \_\_\_\_\_ in an envelope addressed to: \_\_\_\_\_

EV382053969-05

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on January 5, 2005  
Date

Beck

Signature \_\_\_\_\_

Typed or printed name of person signing Certificate

Registration Number, if applicable

Telephone Number

**Note:** Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Request for Withdrawal of Notice of Abandonment (3 pages)  
Exhibits A-F (19 pages)  
Fee Transmittal (1 page)  
Return Postcard



|  |                  |                          |                   |
|--|------------------|--------------------------|-------------------|
| <b>FEE TRANSMITTAL</b><br><b>For FY 2005</b>                                   |                  | <b>Complete if Known</b> |                   |
|  |                  | Application Number       | 10/615,213        |
|  |                  | Filing Date              | July 7, 2003      |
|  |                  | First Named Inventor     | Moise Azria       |
|  |                  | Examiner Name            | P. J. Killos      |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27 | Art Unit         | 1625                     |                   |
| <b>TOTAL AMOUNT OF PAYMENT</b>   | <b>(\$)</b> 0.00 | Attorney Docket No.      | 01946/100G906-US2 |

|   |   |
|---|---|
| <b>METHOD OF PAYMENT</b> (check all that apply)   |   |
| <input type="checkbox"/> Check  | <input type="checkbox"/> Credit Card  |
| <input type="checkbox"/> Money Order  | <input type="checkbox"/> None   |
| <input type="checkbox"/> Other (please identify): _____   |   |
| <input checked="" type="checkbox"/> Deposit Account   | Deposit Account Number: 04-0100   |
| Deposit Account Name: Darby & Darby P.C.  |   |
| For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)                |   |
| <input type="checkbox"/> Charge fee(s) indicated below  | <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee |
| <input checked="" type="checkbox"/> Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 | <input checked="" type="checkbox"/> Credit any overpayments                       |

|   |                     |   |                      |                                  |                         |                     |                       |
|---|---------------------|---|----------------------|----------------------------------|-------------------------|---------------------|-----------------------|
| <b>FEE CALCULATION</b>  |                     |   |                      |                                  |                         |                     |                       |
| <b>1. BASIC FILING, SEARCH, AND EXAMINATION FEES</b>  |                     |   |                      |                                  |                         |                     |                       |
|   | <b>FILING FEES</b>  |   | <b>SEARCH FEES</b>   |                                  | <b>EXAMINATION FEES</b> |                     |                       |
|   |                     | <b>Small Entity</b>                                     |                      | <b>Small Entity</b>              |                         | <b>Small Entity</b> |                       |
| <b>Application Type</b>   | <b>Fee (\$)</b>     | <b>Fee (\$)</b>   | <b>Fee (\$)</b>      | <b>Fee (\$)</b>                  | <b>Fee (\$)</b>         | <b>Fee (\$)</b>     | <b>Fees Paid (\$)</b> |
| Utility   | 300                 | 150   | 500                  | 250                              | 200                     | 100                 | _____                 |
| Design  | 200                 | 100   | 100                  | 50                               | 130                     | 65                  | _____                 |
| Plant   | 200                 | 100   | 300                  | 150                              | 160                     | 80                  | _____                 |
| Reissue   | 300                 | 150   | 500                  | 250                              | 600                     | 300                 | _____                 |
| Provisional   | 200                 | 100   | 0                    | 0                                | 0                       | 0                   | _____                 |
| <b>2. EXCESS CLAIM FEES</b>   |                     |   |                      |                                  |                         |                     |                       |
| <b>Fee Description</b>  |                     |   |                      |                                  |                         | <b>Small Entity</b> |                       |
|   |                     |   |                      |                                  |                         | <b>Fee (\$)</b>     | <b>Fee (\$)</b>       |
| Each claim over 20 (including Reissues)   |                     |   |                      |                                  |                         | 50                  | 25                    |
| Each independent claim over 3 (including Reissues)  |                     |   |                      |                                  |                         | 200                 | 100                   |
| Multiple dependent claims   |                     |   |                      |                                  |                         | 360                 | 180                   |
| <b>Total Claims</b>   | <b>Extra Claims</b> | <b>Fee (\$)</b>   | <b>Fee Paid (\$)</b> | <b>Multiple Dependent Claims</b> |                         |                     |                       |
| _____ - 28 = _____  | x _____             | = _____   |                      | <b>Fee (\$)</b>                  | <b>Fee Paid (\$)</b>    |                     |                       |
| <b>Indep. Claims</b>  | <b>Extra Claims</b> | <b>Fee (\$)</b>   | <b>Fee Paid (\$)</b> |                                  |                         |                     |                       |
| _____ - 4 = _____   | x _____             | = _____   |                      |                                  |                         |                     |                       |
| <b>3. APPLICATION SIZE FEE</b>  |                     |   |                      |                                  |                         |                     |                       |
| If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). |                     |   |                      |                                  |                         |                     |                       |
| <b>Total Sheets</b>   | <b>Extra Sheets</b> | <b>Number of each additional 50 or fraction thereof</b> | <b>Fee (\$)</b>      | <b>Fee Paid (\$)</b>             |                         |                     |                       |
| _____ - 100 = _____   | /50                 | _____ (round up to a whole number) x                    | _____ = _____        |                                  |                         |                     |                       |
| <b>4. OTHER FEE(S)</b>  |                     |   |                      |                                  |                         |                     |                       |
| Non-English Specification, \$130 fee (no small entity discount)   |                     |   |                      |                                  |                         |                     | <b>Fees Paid (\$)</b> |
| Other (e.g., late filing surcharge): _____  |                     |   |                      |                                  |                         |                     |                       |

|                     |                  |                                   |                 |
|---------------------|------------------|-----------------------------------|-----------------|
| <b>SUBMITTED BY</b> |                  |                                   |                 |
| Signature           |                  | Registration No. (Attorney/Agent) | 54,781          |
| Name (Print/Type)   | Jason C. Chumney | Telephone                         | (212) 527-7700  |
|                     |                  | Date                              | January 5, 2005 |

|                        |              |
|------------------------|--------------|
| Express Mail Label No. | Dated: _____ |
|------------------------|--------------|



UNITED STATES PATENT AND TRADEMARK OFFICE

*Jason Chumney*  
*01946/180690US2*

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/615,213      | 07/07/2003  | William E. Bay       | 1946/1G906-US2      | 8060             |

7590 12/29/2004

DARBY & DARBY P.C.  
805 Third Avenue  
New York, NY 10022

EXAMINER

KILLOS, PAUL J

ART UNIT PAPER NUMBER

DUE: *PETITION TO REVIVE*

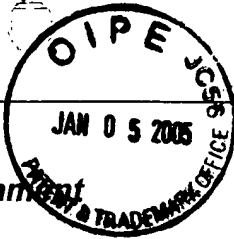
Docketed on *1/3* by *DP* for DATE MAILED: 12/29/2004

Docketed without file ☐

Attorney \_\_\_\_\_

Please find below and/or attached an Office communication concerning this application or proceeding.





# Notice of Abandonment

Application No.

10/615,213

Examiner

Paul J. Killos

Applicant(s)

BAY ET AL.

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 23 June 2004.
  - (a) ☐ A reply was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply (including a total extension of time of \_\_\_\_\_ month(s)) which expired on \_\_\_\_\_.
  - (b) ☐ A proposed reply was received on \_\_\_\_\_, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.  
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
  - (c) ☐ A reply was received on \_\_\_\_\_ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
  - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
  - (a) ☐ The issue fee and publication fee, if applicable, was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
  - (b) ☐ The submitted fee of \$ \_\_\_\_\_ is insufficient. A balance of \$ \_\_\_\_\_ is due.  
The issue fee required by 37 CFR 1.18 is \$ \_\_\_\_\_. The publication fee, if required by 37 CFR 1.18(d), is \$ \_\_\_\_\_.  
(c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
  - (a) ☐ Proposed corrected drawings were received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply.
  - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on \_\_\_\_\_ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

Paul J. Killos  
Primary Examiner  
Art Unit: 1625

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



Atty Docket No.: 01946/100G906-US2

Applicant: William E. Bay et al.

Appln: 10/615,213 Filed: Jul. 7, 2003

Title: DISODIUM SALTS, MONOHYDRATES, AND  
ETHANOL SOLVATES FOR DELIVERING ACTIVE  
AGENTS

**Documents:**

Fee Transmittal for FY 2005 (1 page);  
Three Month Request for Extension of Time Under  
37 CFR 1.136(a) (1 page);  
Amendment in Response to Non-Final Office Action (8 pages);  
Amendment Transmittal Letter (1 page)  
Certificate of Express Mailing (1 page); and  
Check No. 7124 for \$1,020.00

Via: Express Mail: Airbill No.

Sender Initials: JCC/sjw Date: December 23, 2004

EV 382054156-us

*B.W. Lee*

|   |   |                            |                             |
|---|---|----------------------------|-----------------------------|
| <b>DARBY &amp; DARBY, P.C.</b>  |   | 1-8-210                    | 7124                        |
| <b>PATENT OFFICE ACCOUNT</b>  |   |                            |                             |
| 805 THIRD AVENUE  |   |                            |                             |
| NEW YORK, NY 10022  |   | DATE <u>12/23/04</u>       |                             |
| PAY TO THE ORDER OF   | <b>COMMISSIONER OF PATENTS &amp; TRADEMARKS</b> |                            | \$ <u>1020.00</u>           |
| <u>One Thousand Twenty</u>  |   | DOLLARS                    | <u>84</u>                   |
| <b>citibank</b>   |   |                            |                             |
| CITIBANK, N.A. BR. #852<br>153 EAST 53RD STREET<br>NEW YORK, NY 10043 |   | The Citigroup Private Bank |                             |
| MEMO  | <u>615,213/100G906US2</u>                       |                            | <u>Gabriella V. Karaszi</u> |
| ⑆021000087⑆   |   | 43348071                   | 7124                        |





Application No. (if known): 10/615,213

Attorney Docket No.: 01946/100G906-US2

## Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. \_\_\_\_\_ In an envelope addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**EJ 382054156-US**

on December 23, 2004  
Date

*B.W. Lee*

Signature

*B.W. LEE*

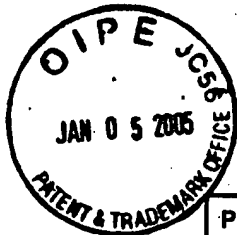
Typed or printed name of person signing Certificate

Registration Number, if applicable \_\_\_\_\_

Telephone Number \_\_\_\_\_

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Fee Transmittal for FY 2005 (1 page);  
Three Month Request for Extension of Time Under  
37 CFR 1.136(a) (1 page);  
Amendment in Response to Non-Final Office Action ( 8 pages);  
Amendment Transmittal Letter (1 page)  
Return Postcard; and  
Check No. 724 for \$1,020.00



**PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)**  
**FY 2005**  
(fees effective on or after October 1, 2004)

Docket Number (Optional)  
01946/100G906-US2

Application Number 10/615,213

Filed July 7, 2003

For **DISODIUM SALTS, MONOHYDRATES, AND ETHANOL SOLVATES FOR DELIVERING ACTIVE AGENTS**

Art Unit 1625

Examiner Paul J. Killos

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

|  | <u>Fee</u> | <u>Small Entity Fee</u> |             |
|--|------------|-------------------------|-------------|
| <input type="checkbox"/> One month (37 CFR 1.17(a)(1))               | \$110.00   | \$55.00                 | \$          |
| <input type="checkbox"/> Two months (37 CFR 1.17(a)(2))              | \$430.00   | \$215.00                | \$          |
| <input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3)) | \$1,020.00 | \$510.00                | \$ 1,020.00 |
| <input type="checkbox"/> Four months (37 CFR 1.17(a)(4))             | \$1,530.00 | \$765.00                | \$          |
| <input type="checkbox"/> Five months (37 CFR 1.17(a)(5))             | \$2,080.00 | \$1,040.00              | \$          |

☐ Applicant claims small entity status. See 37 CFR 1.27.

☒ A check in the amount of the fee is enclosed.

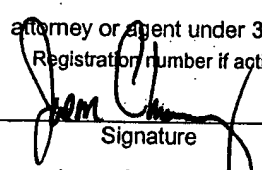
☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 04-0100. I have enclosed a duplicate copy of this sheet.

I am the ☐ applicant/inventor.  
☐ assignee of record of the entire interest. See 37 CFR 3.71.  
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).  
☐ attorney or agent of record. Registration Number \_\_\_\_\_

☒ attorney or agent under 37 CFR 1.34(a).  
Registration number if acting under 37 CFR 1.34(a) 54,781

  
\_\_\_\_\_  
Signature  
Jason C. Chumney  
\_\_\_\_\_  
Typed or printed name

December 23, 2004

Date

(212) 527-7700

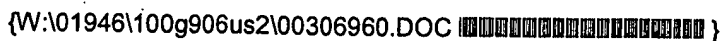
Telephone Number

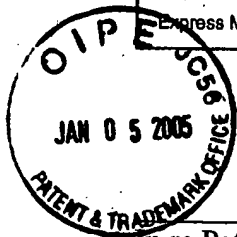
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of 1 forms are submitted.

Express Mail Label No.

Dated: \_\_\_\_\_





Express Mail Label No. \_\_\_\_\_ Dated: \_\_\_\_\_

Docket No.: 01946/100G906-US2  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
William E. Bay et al.

Application No.: 10/615,213

Confirmation No.: 8060

Filed: July 7, 2003

Art Unit: 1625

For: DISODIUM SALTS, MONOHYDRATES, AND  
ETHANOL SOLVATES FOR DELIVERING  
ACTIVE AGENTS

Examiner: Paul J. Killos

**AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INTRODUCTORY COMMENTS**

In response to the Office Action mailed June 23, 2004, please amend the above-identified U.S. patent application as follows:

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

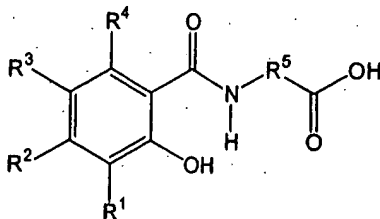
**Remarks** begin on page 7 of this paper.

This submission is accompanied by a request for a three-month extension of time.

**AMENDMENTS TO THE CLAIMS**

Please amend the claims so that they read as follows:

1. (Original): A disodium salt of a delivery agent having the formula



wherein

R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, and R<sup>4</sup> are independently hydrogen, -OH, -NR<sup>6</sup>R<sup>7</sup>, halogen, C<sub>1</sub>-C<sub>4</sub> alkyl, or C<sub>1</sub>-C<sub>4</sub> alkoxy;

R<sup>5</sup> is a substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkylene, substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkenylene, substituted or unsubstituted C<sub>1</sub>-C<sub>12</sub> alkyl(arylene), or substituted or unsubstituted aryl(C<sub>1</sub>-C<sub>12</sub> alkylene); and

R<sup>6</sup> and R<sup>7</sup> are independently hydrogen, oxygen, or C<sub>1</sub>-C<sub>4</sub> alkyl.

2. (Original): The disodium salt of claim 1, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

3. (Original): The disodium salt of claim 1, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

4. (Original): The disodium salt of claim 1, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

5. (Original): An ethanol solvate of the disodium salt of claim 1.

6. (Original): The ethanol solvate of claim 5, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

7. (Original): The ethanol solvate of claim 5, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

8. (Original): The ethanol solvate of claim 5, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

9. (Original): A monohydrate of the disodium salt of claim 1.

10. (Original): The monohydrate of claim 9, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

11. (Original): The monohydrate of claim 9, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

12. (Original): The monohydrate of claim 9, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

13. (Original): A composition comprising at least about 50% by weight of the disodium salt of claim 1, based upon 100% total weight of delivery agent and salts thereof in the composition.

14. (Original): The composition of claim 13, wherein the composition comprises at least about 90% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

15. (Original): A composition comprising:

(a) the disodium salt of claim 1, ethanol solvate thereof, or monohydrate thereof; and

(b) at least one active agent.

16. (Original): The composition of claim 15, wherein the composition comprises at least about 50% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

17. (Original): The composition of claim 16, wherein the composition comprises at least about 90% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

18. (Original): The composition of claim 15, wherein the composition comprises at least about 90% by weight of the monohydrate, based upon 100% total weight of hydrate of the disodium salt of the delivery agent in the composition.

19. (Original): The composition of claim 15, wherein the active agent is selected from the group consisting of growth hormones; human growth hormones; recombinant human growth hormones; bovine growth hormones; porcine growth hormones; growth hormone-releasing hormones; interferons;  $\alpha$ -interferon;  $\beta$ -interferon;  $\gamma$ -interferon; interleukin-1; interleukin-2; insulin; porcine insulin; bovine insulin; human insulin; human recombinant insulin; insulin-like growth factor; IGF-1; heparin; unfractionated heparin; heparinoids; dermatans; chondroitins; low molecular weight heparin; very low molecular weight heparin; ultra low molecular weight heparin; calcitonin; salmon calcitonin; eel calcitonin; human calcitonin; porcine calcitonin; erythropoietin; atrial natriuretic factor; antigens; monoclonal antibodies; somatostatin; protease inhibitors; adrenocorticotropin; gonadotropin releasing hormone; oxytocin; leutinizing-hormone-releasing-hormone; follicle stimulating hormone; glucocerebrosidase; thrombopoietin; filgrastim; prostaglandins; cyclosporin; vasopressin; cromolyn sodium;





Claims 23-28 (Canceled)

29. (New): A method for administering salmon calcitonin to an animal in need thereof, the method comprising administering orally to the animal a composition comprising:

(a) N-(5-chlorosalicyloyl)-8-aminocaprylic acid, wherein N-(5-chlorosalicyloyl)-8-aminocaprylic acid comprises at least about 96% by weight of the disodium salt of N-(5-chlorosalicyloyl)-8-aminocaprylic acid; and

(b) salmon calcitonin.

**REMARKS****Status of the Claims**

Claims 23-28 have been canceled without prejudice or disclaimer. Claim 29 has been added, support for which can be found, for example, on page 8, lines 16-23; and page 5, lines 8-12.

As amended the claims are drawn to two inventions: (1) claims 1-22 are drawn to disodium salts of delivery agents, including ethanol solvates and monohydrates thereof, and compositions and unit dosage forms containing the same; and (2) claim 29 is drawn to a method for administering salmon calcitonin.

**Rejections Under 35 U.S.C. §102**

Claims 1, 2, 4, 5, 7-9 and 11-28 stand rejected as anticipated by WO 96/30036. The Examiner contends that disodium salts are formed in situ when the compounds are treated with sodium hydroxide. Disodium salts are not explicitly disclosed or suggested in WO 96/30036. The claimed compounds have two ionizable sites, one at the carboxyl terminus and one at the 2-hydroxy group on the phenyl ring. Treatment with the amount of sodium hydroxide specified in WO 96/30036 will not form the disodium salt because of the extremely low reaction constant ( $K_a$ ) of the 2-hydroxy group. Therefore WO 96/30036 does not anticipate claims 1, 2, 4, 5, 7-9 and 11-28. Accordingly applicants request withdrawal of this rejection.

In view of the above remarks, applicant believes the pending application is in condition for allowance.

Dated: December 23, 2004

Respectfully submitted,

By

Jason C. Chumney

Registration No.: 54,781

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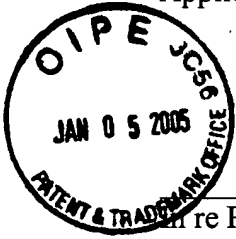


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Docket No.: 01946/100G906-US2



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Entre Patent Application of:  
William E. BAY et al.

Application No.: 10/615,213

Confirmation No.: 8060

Filed: July 7, 2003

Art Unit: 1625

For: **DISODIUM SALTS, MONOHYDRATES, AND  
ETHANOL SOLVATES FOR DELIVERING  
ACTIVE AGENTS**

**Examiner: Paul J. KILLOS**

## DECLARATION OF BRUCE W. LEE

**Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**

Dear Sir:

I, Bruce W. Lee, declare as follows:

1. I am employed as a Docketing Clerk at Darby & Darby, P.C. I make this declaration in support of the accompanying REQUEST FOR WITHDRAWAL OF NOTICE OF ABANDONMENT, which seeks the withdrawal of the NOTICE OF ABANDONMENT mailed on December 29, 2004, in the above-identified application.

2. A true copy of the Notice of Abandonment mailed December 29, 2004 is attached as Exhibit A. The Notice of Abandonment states that the applicant failed to timely file a proper reply to the Office Action mailed on June 23, 2004, and that no reply has been received.

3. A true copy of the Amendment In Response to Non-Final Office Action submitted on December 23, 2004 is attached as Exhibit C. Exhibit C also includes a Petition for a Three Month

Extension of Time, and an executed Certificate of Express Mailing Under 37 CFR 1.10 dated December 23, 2004, which includes my signature.

4. In accordance with our office procedure, the secretary of the attorney who prepared the papers being transmitted to the U.S. Patent and Trademark Office ("USPTO") would have brought the papers to the docketing department. The docketing department would have reviewed the papers for completeness and, if satisfied, would have imprinted, signed, and dated the Express Mail Certificate. The docketing department would then have placed it in a properly addressed postage paid envelope for mailing to the USPTO. Incomplete or unsigned papers would not be placed in the envelope, but would be returned to the attorney. At the end of the day, the docketing department forwards the USPTO envelope to our services department to be mailed with the U.S. Postal Service (USPS).

5. Attached as Exhibit B is a true copy of a self addressed postcard stamped with Express Mail tracking number EV 382054156 and a true copy of a check for \$1020.00. These items would have accompanied the other papers, and I would have considered the papers incomplete in their absence.

6. Attached as Exhibit D is a true copy of an Express Mail label which lists the same tracking number, EV 382054156, as stamped on the self-addressed postcard (Exhibit B). This Express Mail label has a USPS mailroom stamp dated December 23, 2004. This confirms that the originals of Exhibits B and C were mailed on that date.

7. The return, stamped postcard has not yet been received by applicant's counsel.

8. Based upon the presence of the Certificate of Express Mailing I signed, the postcard I signed, and the USPS-stamped Express Mail receipt, it may be concluded that the originals of Exhibits B and C were timely filed on December 23, 2004, in accordance with normal procedures at Darby & Darby.

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the

knowledge that willful and false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: January 5, 2005

Respectfully submitted,

By Bruce W. Lee  
Bruce W. Lee  
Docketing Clerk  
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